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510(k) SUMMARY
FMS PORTAPRES AMBULATORY NONINVASIVE BLOOD PRESSURE MONITOR

This 510(k) summary is being submitted in accordance with the requirements of SMDA and 21CFR § 807.92

I. NAME OF SUBMITTER

FMS, Finapres Medical Systems BV
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Date Prepared: 9/27/02

II. DEVICE NAME AND CLASSIFICATION

Proprietary Name:	Portapres Ambulatory Continuous Non Invasive Blood Pressure Monitor
Common or Usual Name:	Continuous Non-Invasive Blood Pressure Monitor
Classification:	Class II; CFR 870.1130, Product Code DXN

III. PREDICATE DEVICES

The Portapres is substantially equivalent in design (methodology) and indications for use to the following devices that have been or still are in commercial distribution:

- Ohmeda 2300 Finapres® Blood Pressure Monitor, Ohmeda Medical, Englewood, CO 80112-5810, K822055
- Ohmeda 2350 Finapres® Blood Pressure Monitor, Ohmeda Medical, Englewood, CO 80112-5810, K880572
- Task Force Monitor 3040, CNSystems Medizintechnik GMBH, Europe, AU, K014063
- (BeatScope software): RODA Monitoring System, Metracor Technologies, Inc., San Diego, CA 921221, K011238

Portapres and Finapres are substantially equivalent in design, methodology, software, manufacture, materials, intended use and principle of operation. The Portapres, the Finapres, and the Task Force Monitor devices are intended for use for continuous monitoring of finger arterial blood pressure, the Portapres in an ambulatory model and the Finapres and Task Force Monitor in stationary models. FMS considers the use of the Portapres to be substantially equivalent to its predicate devices, the Ohmeda 2300 and 2350 Finapres and the CNSystems Task Force Monitor, and considers the BeatScope software cardiac output technology to be equivalent to the RODA Monitoring System cardiac output technology.

IV. DESCRIPTION

Portapres is a portable, battery-powered device to record continuous non-invasive arterial blood pressure. Portapres is intended for 24-hour continuous recordings in ambulatory subjects. The device includes a Neoprene belt to be worn around the waist, with compartments for the Main Unit with electronics and memory card, a Pump Unit with an air pump, and a NiCd or Li battery pack. Connected to the waist belt Main Unit and Pump Unit is a Wrist Unit, used to interface with the signals from the electronics and air supply in the waist belt to the finger cuffs. The Wrist Unit then connects to a finger cuff, which consists of an inflatable air bladder and an infrared photoplethysmograph. The plethysmograph measures the finger arterial volume which varies with the patient's blood pressure. The Wrist Unit controls the pressure in the cuff bladder so as to keep the arterial volume constant at a level (the setpoint) determined during startup. The Wrist Unit contains a pressure transducer that measures the cuff pressure as an indirect measure of the patient's blood pressure. Also connected to the Wrist Unit is a hydrostatic height correction unit that compensates for the hydrostatic component of the blood pressure in the finger when this is not at heart level. This allows the patient free hand movement in ambulatory applications.

Pressure and volume signals from the finger cuffs are routed from the Wrist Unit to the Main Unit microprocessor for pump control and data acquisition purposes. The

microprocessor has an internal flash memory card for storage of blood pressure wave form data.

The Main Unit is equipped with an RS232 serial interface to transfer the data stored in the flash memory card via a Control Unit to a PC and to allow remote control of the Portapres.

V. INTENDED USE

The Portapres Ambulatory Continuous Non-Invasive Blood Pressure Monitor is intended to provide the user with continuous, noninvasive blood pressure and pulse rate monitoring. The Portapres enables 24-hour continuous ambulatory measurements.
The PC-based BeatScope software used with the data from the device provides Modelflow-based computation of real-time and beat-to-beat blood pressure as well as hemodynamic parameters from the pressure waveform, including, cardiac output and total peripheral resistance.

VI. TECHNOLOGICAL CHARACTERISTICS

No new technology, materials, or change in efficacy have been introduced by FMS in the manufacture of the FMS Portapres Ambulatory Continuous Noninvasive Blood Pressure Monitor. The design, form, and materials of the monitor are equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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FMS, Finapres Medical Systems BV
c/o Ms. Christine Emanuel
TECSA Technical Services
1205 De La Vina Street
Santa Barbara, CA 93101

Re: K023338
Trade Name: Portapres Ambulatory Continuous Non Invasive Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II (two)
Product Code: DXN
Dated: March 5, 2003
Received: March 10, 2003

Dear Ms. Emanuel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K023338

Include the following "Indications For Use" page that contains the applicant's name, name of the device and the intended use of the device. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the "indications for use" statement.
*For a new submission, do NOT fill in the 510(k) number blank.

INDICATIONS FOR USE

Applicant: FMS, Finapres Medical Systems BV

510(k) Number (if known): N/A*

Device Name: Portapres Ambulatory Continuous Non-Invasive Blood Pressure Monitor

Indications For Use:

The Portapres Ambulatory Continuous Non-Invasive Blood Pressure Monitor is intended to provide the user with continuous, noninvasive blood pressure and pulse rate monitoring. The Portapres enables 24-hour continuous ambulatory measurements.
The PC-based BeatScope software used with the data from the device provides Modelflow-based computation of real-time and beat-to-beat blood pressure as well as hemodynamic parameters from the pressure waveform, including, cardiac output and total peripheral resistance.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023338

Prescription Use X
Per 21 CFR 801.109

OR

Over-the-Counter _____